



Health Care General Committee

**Wednesday, January 11, 2006
10:45 AM – 11:45 AM
306 HOB**

ACTION PACKET

COMMITTEE MEETING REPORT

Health Care General Committee

1/11/2006 10:45:00AM

Location: 306 HOB

Attendance:

	<i>Present</i>	<i>Absent</i>	<i>Excused</i>
Gayle Harrell (Chair)	X		
Loranne Ausley	X		
Kim Berfield	X		
Joyce Cusack	X		
Denise Grimsley	X		
D. Alan Hays	X		
Paige Kreegel	X		
Stan Mayfield		X	
Dave Murzin	X		
Julio Robaina	X		
Juan Zapata	X		
Totals:	10	1	0

Committee meeting was reported out: Wednesday, January 11, 2006 1:15:43PM

COMMITTEE MEETING REPORT

Health Care General Committee

1/11/2006 10:45:00AM

Location: 306 HOB

HB 371 : Cancer Drug Donation Program

☒ Favorable With Committee Substitute

	Yea	Nay	No Vote	Absentee Yea	Absentee Nay
Loranne Ausley	X				
Kim Berfield	X				
Joyce Cusack	X				
Denise Grimsley	X				
D. Alan Hays	X				
Paige Kreegel	X				
Stan Mayfield			X		
Dave Murzin	X				
Julio Robaina	X				
Juan Zapata	X				
Gayle Harrell (Chair)	X				
Total Yeas: 10		Total Nays: 0			

HB 371 Amendments

Amendment 01

☒ Adopted Without Objection

Appearances:

HB 371--Cancer Drug Donation Program

Larry Gonzalez, Attorney/Lobbyist (Lobbyist) - Proponent

Florida Society of Health-System Pharmacists

215 South Monroe Street

Tallahassee FL 32301

Phone: (850) 222-0720

HB 371--Cancer Drug Donation Program

Paul Hull, VP, Advocacy & Public Policy (Lobbyist) - Proponent

American Cancer Society, Florida Division

3709 W. Jetton Avenue

Tampa FL 33629

Phone: (813) 382-9235

HB 371--Cancer Drug Donation Program

Chris Nuland (WAIVED TIME IN SUPPORT OF THE BILL) - Proponent

Florida Public Health Association

1000 Riverside Avenue #115

Jacksonville FL 32204

Phone: (904) 355-1555

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COMMITTEE MEETING REPORT

Health Care General Committee

1/11/2006 10:45:00AM

Location: 306 HOB

HB 371--Cancer Drug Donation Program

Aurelio Ortiz, MD (WAIVED TIME IN SUPPORT OF THE BILL) (State Employee) - Proponent

American College of Physicians

2535 Beautyberry Circle East

Jacksonville FL 32246

Phone: (904) 992-7011

HB 371--Cancer Drug Donation Program

James Mosteller (WAIVED TIME IN SUPPORT OF THE BILL) (Lobbyist) - Proponent

Florida Hospices

3816 Shamrock Street West

Tallahassee FL 32309

Phone: (950) 345-7885

HB 371--Cancer Drug Donation Program

Chris Hansen (Lobbyist) - Proponent

Bayer

215 S. Monroe Street #110

Tallahassee FL 32301

Phone: (850) 224-7091

Committee meeting was reported out: Wednesday, January 11, 2006 1:15:43PM

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01 (for drafter's use only)

Bill No. **HB 371**

COUNCIL/COMMITTEE ACTION

ADOPTED _____ (Y/N)
ADOPTED AS AMENDED _____ (Y/N)
ADOPTED W/O OBJECTION ☒ (Y/N)
FAILED TO ADOPT _____ (Y/N)
WITHDRAWN _____ (Y/N)
OTHER _____

ADOPTED

01/11/2006

Council/Committee hearing bill: Health Care General
Representative(s) Harrell offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:
Section 1. Section 381.94, Florida Statutes, is created to
read:

381.94 Cancer Drug Donation Program.--

(1) This act may be cited as the "Cancer Drug Donation
Program Act."

(2) There is created a Cancer Drug Donation Program within
the Department of Health for the purpose of authorizing and
facilitating the donation of cancer drugs and supplies to
eligible patients.

(3) As used in this section:

(a) "Cancer drug" means a prescription drug whose approved
application has become effective under s. 505 of the federal
Food, Drug and Cosmetic Act and is used to treat cancer or its
side effects or is used to treat the side effects of a
prescription drug used to treat cancer or its side effects.
Cancer drug pursuant to this definition shall not include a
substance in Schedule II, III, IV or V pursuant to s. 893.03.

01/10/2006 6:58 pm

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23 (b) Closed drug delivery system means a system in which the
24 actual control of the unit dose medication package is maintained
25 by the facility rather than by the individual patient.

26 (c) "Department" means the Department of Health.

27 (d) "Donor" means a patient or patient representative who
28 donates cancer drugs or supplies needed to administer cancer
29 drugs that have been maintained within a closed delivery system,
30 health care facilities, nursing homes, hospices, or hospitals,
31 with closed drug delivery systems, or a pharmacy, drug
32 manufacturer, medical device manufacturer or supplier, or
33 wholesaler of drugs or supplies, in accordance with this
34 section. A donor also includes a physician licensed under
35 Chapter 458 or 459 who receives cancer drugs or supplies
36 directly from a drug manufacturer, drug wholesaler or pharmacy.

37 (e) "Eligible patient" means a person who the department
38 determines is eligible to receive cancer drugs from the program.

39 (f) "Health care facility" means a health care facility
40 licensed under chapter 395.

41 (g) "Health care clinic" means a health care clinic
42 licensed under part XIII of chapter 400.

43 (h) "Hospice" means a corporation licensed under part VI
44 of chapter 400.

45 (i) "Hospital" means a facility as defined in s. 395.002
46 and licensed under chapter 395.

47 (j) "Nursing home" means a facility licensed under part II
48 of chapter 400.

49 (k) "Participant facility " means a class II institutional
50 hospital pharmacy that has elected to participate in the program
51 and that accepts donated cancer drugs and supplies under the
52 rules adopted by the department for the program.

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(l) "Pharmacist" means a pharmacist licensed under chapter 465.

(m) "Pharmacy" means an entity licensed under chapter 465.

(n) "Prescribing practitioner" means a physician licensed under chapter 458 or any other medical professional with authority under state law to prescribe cancer medication.

(o) "Prescription drug" means a drug as defined in s. 465.003(8).

(p) "Program" means the Cancer Drug Donation Program created by this section.

(q) "Supplies" means any supplies used in the administration of a cancer drug.

(4) Any donor may donate cancer drugs or supplies to a participant facility that elects to participate in the program and meets criteria established by the department for such participation. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program. A participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital.

(5) The cancer drug or supplies donated to the program may be prescribed only by a prescribing practitioner for use by an eligible patient and may be dispensed only by a pharmacist.

(6)(a) A cancer drug may only be accepted or dispensed under the program if such drug is in its original, unopened, sealed container, or in a tamper-evident unit dose packaging, except that a cancer drug packaged in single unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging if unopened with tamper-resistant packaging intact.

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83 (b) A cancer drug may not be accepted or dispensed under
84 the program if such drug bears an expiration date that is less
85 than 6 months after the date the drug was donated or if the drug
86 is appears to have been tampered with or mislabeled as
87 determined in paragraph (c).

88 (c) Prior to being dispensed to an eligible patient, the
89 cancer drug or supplies donated under the program shall be
90 inspected by a pharmacist to determine that the drug and
91 supplies do not appear to have been tampered with or mislabeled.

92 (d) A dispenser of donated cancer drugs or supplies may
93 not submit a claim or otherwise seek reimbursement from any
94 public or private third-party payor for donated cancer drugs or
95 supplies dispensed to any patient under the program, and a
96 public or private third-party payor is not required to provide
97 reimbursement to a dispenser for donated cancer drugs or
98 supplies dispensed to any patient under the program.

99 (7)(a) A donation of cancer drugs shall be made only at a
100 participant facility. A participant facility may decline to
101 accept a donation. A participant facility that accepts donated
102 cancer drugs or supplies under the program shall comply with all
103 applicable provisions of state and federal law relating to the
104 storage and dispensing of the donated cancer drugs or supplies.

105 (b) A participant facility that voluntarily takes part in
106 the program may charge a handling fee sufficient to cover the
107 cost of preparation and dispensing of cancer drugs or supplies
108 under the program. The fee shall be established in rules adopted
109 by the department.

110 (8) The department, upon the recommendation of the Board
111 of Pharmacy, shall adopt rules to carry out the provisions of
112 this section. Initial rules under this section shall be adopted

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no later than 90 days after the effective date of this act. The rules shall include, but not be limited to:

(a) Eligibility criteria, including a method to determine priority of eligible patients under the program.

(b) Standards and procedures for participant facilities that accept, store, distribute, or dispense donated cancer drugs or supplies.

(c) Necessary forms for administration of the program, including, but not limited to, forms for use by entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program.

(d) The maximum handling fee that may be charged by a participant facility that accepts and distributes or dispenses donated cancer drugs or supplies.

(e) Categories of cancer drugs and supplies that the program will accept for dispensing, however, the department may exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.

(f) Maintenance and distribution of the participant facility registry established in subsection (10).

(9) A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, or by any other prescription drug program funded in whole or in part by the federal government, or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted, or a certain cancer drug or cancer supply is not covered by the prescription drug program, or is ineligible to participate in the program created under this section.

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143 (10) The department shall establish and maintain a
144 participant facility registry for the program. The participant
145 facility registry shall include the participant facility's name,
146 address, and telephone number. The department shall make the
147 participant facility registry available on the department's
148 website to any participant facility wishing to donate cancer
149 drugs or supplies to the program. The department's web site
150 shall also contain links to cancer drug manufacturers that offer
151 drug assistance program or offer free medication.

152 (11) Any donor of cancer drugs or supplies, or any
153 participant facility in the program, who exercises reasonable
154 care in donating, accepting, distributing, or dispensing cancer
155 drugs or supplies under the program and the rules adopted under
156 this section shall be immune from civil or criminal liability
157 and from professional disciplinary action of any kind for any
158 injury, death, or loss to person or property relating to such
159 activities.

160 (12) A pharmaceutical or cancer supply manufacturer is not
161 liable for any claim or injury arising from the donation and use
162 of any cancer drug under this section, including, but not
163 limited to, liability for failure to transfer or communicate
164 product or consumer information regarding the donated drug or
165 supply, as well as the expiration date of the donated drug or
166 supply.

167 (13) If any conflict exists between the provisions
168 contained in s.381.94 and provisions in Chapter 465 or 499, the
169 provisions contained in s. 381.94 shall control as to the
170 operation of the Cancer Drug Donation Program.

171 Section 2. This act shall take effect July 1, 2006.
172
173

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===== T I T L E A M E N D M E N T =====

Remove the entire title and insert:

A bill to be entitled

An act relating to the Cancer Drug Donation Program;
creating s. 381.94, F.S.; providing a short title;
creating the Cancer Drug Donation Program; providing a
purpose; providing definitions; providing conditions for
donation of cancer drugs and supplies to the program;
providing conditions for the acceptance of cancer drugs
and supplies into the program, inspection of cancer drugs
and supplies, and dispensation of cancer drugs and
supplies to eligible patients; requiring a participant
facility that accepts donated drugs and supplies through
the program to comply with certain state and federal laws;
authorizing a participating participant facility to charge
fees under certain conditions; requiring the Department of
Health, upon recommendation of the Board of Pharmacy, to
adopt certain rules; providing for the ineligibility of
certain persons to receive donated drugs; requiring the
department to establish and maintain a participant
facility registry; providing for the contents and
availability of the participant facility registry;
providing immunity from civil and criminal liability for
donors, pharmaceutical manufacturers, or cancer supply
manufacture in certain circumstances; providing that in
the event of conflict between the provisions in s.381.94
and provisions in Chapter 465 or 499, the provisions in s.
381.94 control; providing an effective date.

COMMITTEE MEETING REPORT

Health Care General Committee

1/11/2006 10:45:00AM

Location: 306 HOB

Other Business Appearance:

Post Hurricane Power Restoration for Special Need Clients

Paul M. Davis (At Request Of Chair) - Information Only

Tampa Electric Company

3013 Folklore Drive

Valrico FL 33594

Phone: (813) 630-6277

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Summary:

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HB 371 Favorable With Committee Substitute

Yeas: 10 Nays: 0

Amendment 01 Adopted Without Objection

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